

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OMB
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Certifier

M. Hawkins

Food and Drug Administration

[Docket No. 02N-0054]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Labeling Requirements for Color Additives (Other Than Hair Dyes) and Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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Labeling Requirements for Color Additives (Other Than Hair Dyes)—21 CFR 70.25 and Petitions—21 CFR 71.1 (OMB Control Number 0910–0185)—Extension

Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or unless the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Color additive petitions are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 (21 CFR 71.1) specifies the information that a petitioner must submit in order to establish the safety of a color additive and to secure the issuance of a regulation permitting its use.

FDA scientific personnel review color additive petitions to ensure that the intended use of the color additive in or on food, drugs, cosmetics, and medical devices is suitable and safe. Color additive petitions were specifically provided for by Congress when it enacted the Color Additive Amendments of 1960 (Public Law 94–295). If FDA stopped accepting color additive petitions or stopped requiring them to contain the information specified in § 71.1, there would be no way to bring new uses of listed color additives or new color additives to market. FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

Respondents are businesses engaged in the manufacture or sale of color additives for use in food, drugs, cosmetics, or medical devices.

In the **Federal Register** of February 28, 2002 (67 FR 9297), the agency requested comments on the proposed collection of information. No comments were received that pertained to this collection of information.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating and Maintenance Costs	Total Hours
70.25	0	1	0	0	0	0
71.1	3	1	3	2,000	\$8,600	6,000
Total						6,000

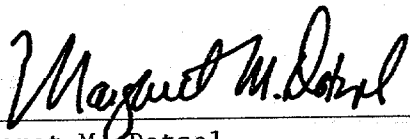
¹ There are no capital costs associated with this collection of information.

This estimate is based on the number of new color additive petitions received in fiscal year 2000 and the total hours expended by petitioners to prepare the petitions. Although the burden varies with the type of petition submitted, a color additive petition involves analytical work and appropriate toxicology studies, as well as the work of drafting the petition itself. Because labeling requirements under § 70.25 for a particular color additive involve information required as part of the color additive petition safety review process, the estimate for the number of respondents is the same for § 70.25 as for § 71.1, and the burden hours for labeling are included in the estimate for § 71.1.

Color additives are subjected to payment of fees for the petitioning process. The listing fee for a color additive petition ranges from \$1,600 to \$3,000, depending on the intended use of the color and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of one category A and two category B color additive petitions are expected per year. The maximum color additive petition fee for a category A petition is \$2,600 and the

maximum color additive petition fee for a category B petition is \$3,000. Since an average of three color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this start-up cost would be less than or equal to \$8,600.

Dated: 5-23-02
May 23, 2002.

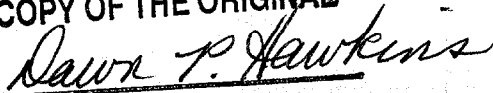


Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Dawn P. Hawkins